510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
k040157

B. Analyte:
C-peptide

C. Type of Test:
Calibration Verification Material for C-peptide

D. Applicant:
Roche Diagnostics Corporation

E. Proprietary and Established Names:
Elecsys® C-Peptide CalCheck

F. Regulatory Information:

1. Regulation section:
   21 CFR §862.1660 Quality control material (assayed and unassayed)
2. Classification:
   Class I
3. Product Code:
   JJX
4. Panel:
   75 – Clinical Chemistry

G. Intended Use:

1. Indication(s) for use:
   The Elecsys® C-Peptide CalCheck is intended for use in the verification of the calibration established by the Elecsys® C-Peptide reagent on the Elecsys® immunoassay systems.

2. Special condition for use statement(s):
   N/A

3. Special instrument Requirements:
   Elecsys® 1010/2010 or MODULAR ANALYTICS E170

H. Device Description:
The Elecsys® C-Peptide CalCheck is a lyophilized product consisting of synthetic human C-peptide in a buffered equine serum matrix (HEPES and preservatives). During manufacture the analytes are spiked into the matrix at the desired

concentration levels: Check 1 ~1 ng/mL, Check 2 ~5 ng/mL, and Check 3 ~30 ng/mL.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   Elecsys® SHBG CalCheck

2. Predicate K number(s):
   K031698

3. Comparison with predicate:
   The intended use, format, preparation of the verifier, instrument systems, and product matrix is the same as the predicate. The analyte is different, and the predicate contains human serum while this product does not.

J. Standard/Guidance Document Referenced (if applicable):

None referenced

K. Test Principle:

Not applicable

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
   - *a. Precision/Reproducibility:*
     N/A
   - *b. Linearity/assay reportable range:*
     N/A
   - *c. Traceability (controls, calibrators, or method):*
     Values for C-peptide are calibrated against the human pro-insulin WHO reference reagent, 1st IRR, code 84/510 (NIBSC) standard. Values are assigned using four each of the three instruments specified above. Two independent series of analyses are performed on each instrument, and two-fold determinations are made for each sample. The target value is then calculated as the median of the determined values.
   - *d. Detection limit:*
     N/A
   - *e. Analytical specificity:*
     N/A
   - *f. Assay cut-off:*
     N/A
   - *g. Other(stability):*
     A modified accelerated testing protocol was used to determine stability of the lyophilized product. C-Peptide master calibrators, which have the same composition and target values as the C-Peptide CalCheck, were stored at 35 C for 3 weeks. They were then

reconstituted and analyzed in duplicate with master calibrators that were stored at -20 C. The product met the acceptance criterion (90%-110% of the value of the frozen calibrators). The sponsor plans on beginning real-time stability testing within a few weeks.

Stability of the reconstituted product was tested by leaving reconstituted product at 20-25 C for five hours after they were prepared and tested in duplicate. The product met the stated acceptance criterion (90%-110% of the initial value) to support the stability claim of 4 hours at 20-25 C.

2. Comparison studies:
   a. *Method comparison with predicate device:*
      N/A
   b. *Matrix comparison:*
      N/A

3. Clinical studies:
   a. *Clinical sensitivity:*
      N/A
   b. *Clinical specificity:*
      N/A
   c. *Other clinical supportive data (when a and b are not applicable):*
      N/A

4. Clinical cut-off:
   N/A

5. Expected values/Reference range:
   Representative Assigned Values of One Lot of Product

Level	Value	Range	Unit
Check 1	0.89	0.70 - 1.07	ng/mL
Check 2	4.28	3.38 – 5.18	ng/mL
Check 3	26.7	21.1 – 32.1	ng/mL

M. Conclusion:

I recommend that the Elecsys® C-Peptide CalCheck be found substantially equivalent to the predicate.